

During cardiac surgery it is often necessary to relieve the heart of its task of pumping blood throughout the body. Partial or complete bypass might also be beneficial to aid the damaged heart to recover and, in those cases where the heart damage is excessive, a permanently implanted artificial heart might be indicated if such systems were available. The characteristics required of such devices need to be defined. Total left-heart bypass of laboratory animals using the servo-controlled roller pump has demonstrated a strong dependence of kidney function, tissue perfusion, and endurance on physiological pulsatile flow. A flow regulation subsystem that automatically adjusts the pump output to the body's demand while maintaining static pressure of the delicate left atrial system within the narrow limits required has been designed and experimentally verified in animals. Pulsing a roller pump to achieve the flow pattern of a normal heart while retaining the simple interface, good blood-handling capabilities, and the established background experience associated with the commonly used roller pump offers an immediate improvement over existing cardiac bypass pumps.

THE DEVELOPMENT OF MECHANICAL PUMPS to supplant the natural heart during cardiac surgery has progressed over the past 15 years to the point where cardiopulmonary bypass is routine in many medical centers. More recently, considerable effort has been directed at developing devices capable of providing partial or total bypass of the heart for longer periods of time and also at developing a permanent artificial heart. Three fundamental design problems of such devices concern the blood damage caused by the pump, the generation of an optimal pulse waveform to best maintain organ function, and the capability to regulate flow output automatically.

While the hemodynamics within the pump play a role in blood damage, it is felt by many that the contact of foreign materials with the blood is very important. Accordingly, a great deal of effort is being directed at developing surfaces which are minimally damaging to the blood and, at the same

time, prevent the deposition of thrombi (clots of blood). Damage can occur to almost all of the constituents of blood, but one convenient measure can be found in the overt destruction of red blood cells called hemolysis. When a red blood cell is destroyed, the oxygen-carrying red hemoglobin it contained is released into plasma where its concentration can be measured. Hemolysis is commonly used as an indicator of pump-induced blood trauma, and criteria have been developed for its careful evaluation.^{1,2}

The physiological necessity for pulsatile flow in a mechanical heart pump has long been a question in the minds of many researchers investigating techniques of implementing cardiac assist and total replacement mechanical heart pumps. Many pumps delivering some form of pulsatile flow are currently under development, yet virtually all cur-

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¹ P. L. Blackshear, F. D. Donnan, and J. Steinbach, "Some Mechanical Effects that Influence Hemolysis," *Trans. Amer. Soc. Artif. Intern. Organs XI*, 1965, 112-120.

² E. F. Bernstein, P. L. Blackshear, and K. H. Keller, "Factors Influencing Erythrocyte Destruction in Artificial Organs," *Amer. J. Surg.* **114**, 1967, 126-138.

A SERVO- CONTROLLED PULSATILE HEART PUMP

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rent surgical procedures requiring cardiopulmonary bypass employ steady flow perfusion.

The waveform requirements for maintaining organ function and tissue viability in long-term perfusions are not known conclusively. A list of journal articles can be gathered to either support or refute the necessity of pulsatile flow. However, most recent, well-controlled studies indicate a need for pulsatile flow.^{3,4} The waveform requirement has far-reaching effects on the complexity and peak power capabilities of future implantable artificial hearts.

In addition to the waveform requirement, it is also necessary that the blood pump adequately adjust the pumping level to adapt to the varying demands of the cardiovascular system. The definition of the control requirements and the means by which they can be automatically implemented is

³ W. G. Rainer, "Pulsatile versus Nonpulsatile Pumping in Mechanical Devices to Assist the Failing Heart," NAS-NRC Publication, 1966, 1283-1294.

⁴ J. K. Trinkle, N. E. Helton, L. R. Bryant, and R. C. Wood, "Metabolic Comparison of Pulsatile and Mean Flow for Cardiopulmonary Bypass," *Circulation* 38, 1968, VI-196.

considered to be a significant problem in the development of mechanical artificial hearts.

The servo-controlled heart pump described here was conceived as a flexible investigative tool to study these problems in laboratory animals undergoing total bypass of the left ventricle. The project has been a joint undertaking between medical researchers of The Johns Hopkins Medical Institutions and control engineers of the Applied Physics Laboratory.

Experimental Pumping System

The basic blood-handling mechanism is the 180° roller pump shown in Fig. 1. This pump is of the type commonly used in cardiopulmonary bypass for open heart surgery and is normally operated at a steady RPM. It consists of a frame with a "U"-shaped fixed rigid surface which supports the blood-filled collapsible cylindrical tube. The roller assembly rotates unidirectionally and causes the roller (which totally occludes the tube) to roll along the tube moving the blood ahead of the moving occlusion.

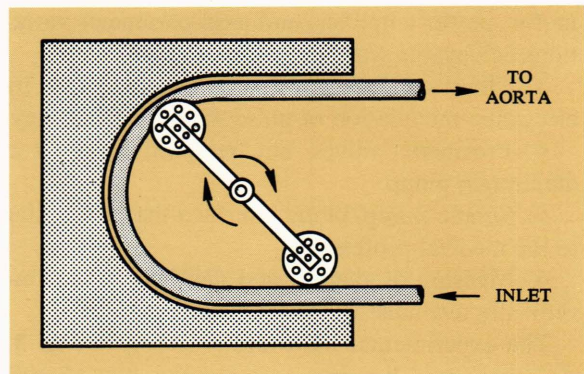


Fig. 1—Roller pump.

The roller assembly of the experimental pump is rotated by a direct drive DC torque motor to allow it to be operated in either a steady-state or pulsatile mode. This highly responsive motor has sufficient acceleration capability to duplicate the extremely rapid initial ejection rate of the normal ventricle. To assist in motor control, a DC tachometer generator mounted on the motor shaft is used to measure the angular velocity of the roller assembly as shown in Fig. 2. This velocity signal, which is proportional to blood flow rate, is fed back and subtracted from an electronically generated desired flow rate signal. The resulting dif-

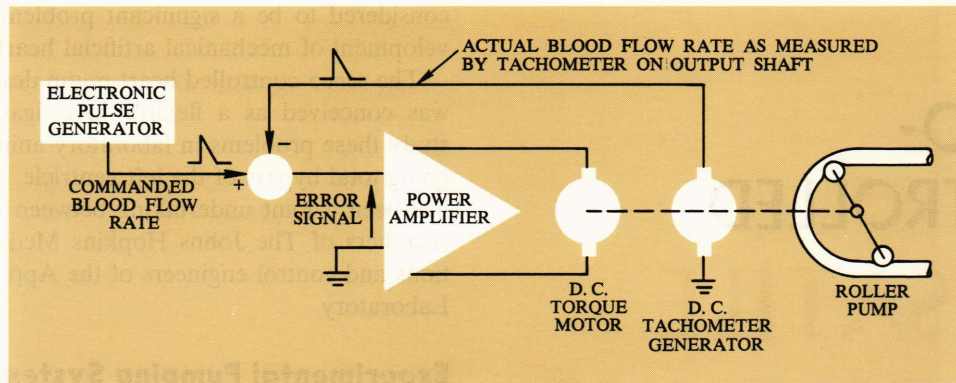


Fig. 2—Block diagram of servo-controlled roller pump.

ference (error signal) is amplified and used to drive the roller pump shaft in order to null the error. Thus, via feedback, the pump output waveform is slaved to the electronically generated flow rate command. The resulting servo-controlled roller pump offers the following features for laboratory research applications:

1. Flexibility of electronically generated pulse waveforms.
2. Immunity of blood pulse waveforms to motor, power amplifier, and load parameter variations achievable with feedback.
3. Flow regulations readily implemented by electronic modulation of pulse width or frequency.
4. Prosthetic valves not required as with a diaphragm pump.
5. Simple pump/blood interface that is familiar to the medical profession.
6. Measure of average and peak flow rate conveniently available using DC tachometer signal.

The experimental hardware is shown in Fig. 3. An aluminum housing encloses the "U"-shaped Dacron-reinforced flexible tube and roller assembly. The torque motor and tachometer, which are connected to the roller arm with a vertical shaft, are mounted below the pump housing. Electronic controls for manual selection of the pulse waveform and meters for monitoring peak and average pump flow rate are conveniently located on the front control panel. The pulse rate and systolic (ejection) duration are manually selectable in discrete steps. Either pulsatile or steady-flow operation may be selected by a front panel switch.

The choice of electronic pulse shaping provides high flexibility in varying the flow pulse shape. The electronic generator was designed to produce the typical triangular-shaped flow pulse of a nor-

mal left ventricle. The pulse generator circuit which produces the desired flow waveform is a conventional solid-state design and basically consists of an astable multivibrator which resets a limited integrator. The pulse generator allows the independent variation of three pump waveform parameters. The pulse rate may be varied from 60 to 170 pulses per minute in steps of 10 pulses per minute by varying the multivibrator frequency. The systolic duration may be varied from 0.1 to 0.35 sec in steps of 0.025 sec by changing the DC bias of the limited integrator input. The peak flow may be varied continuously from 0 to 25 l/min by attenuating the integrator output waveform with a potentiometer. Further, steady

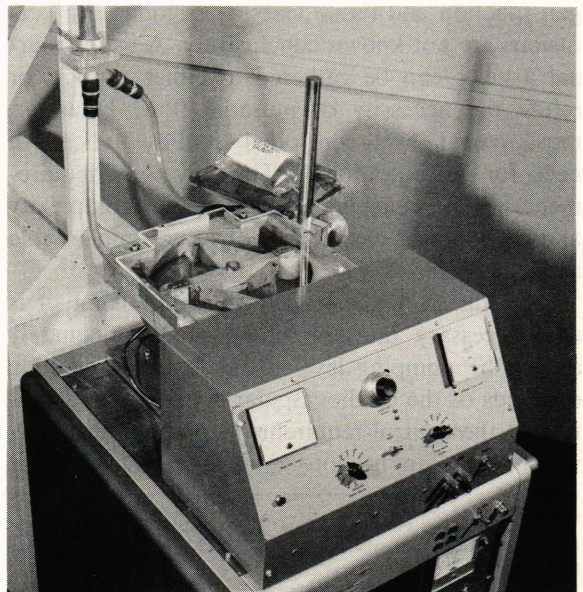


Fig. 3—JHMI/APL pulsatile roller pump.

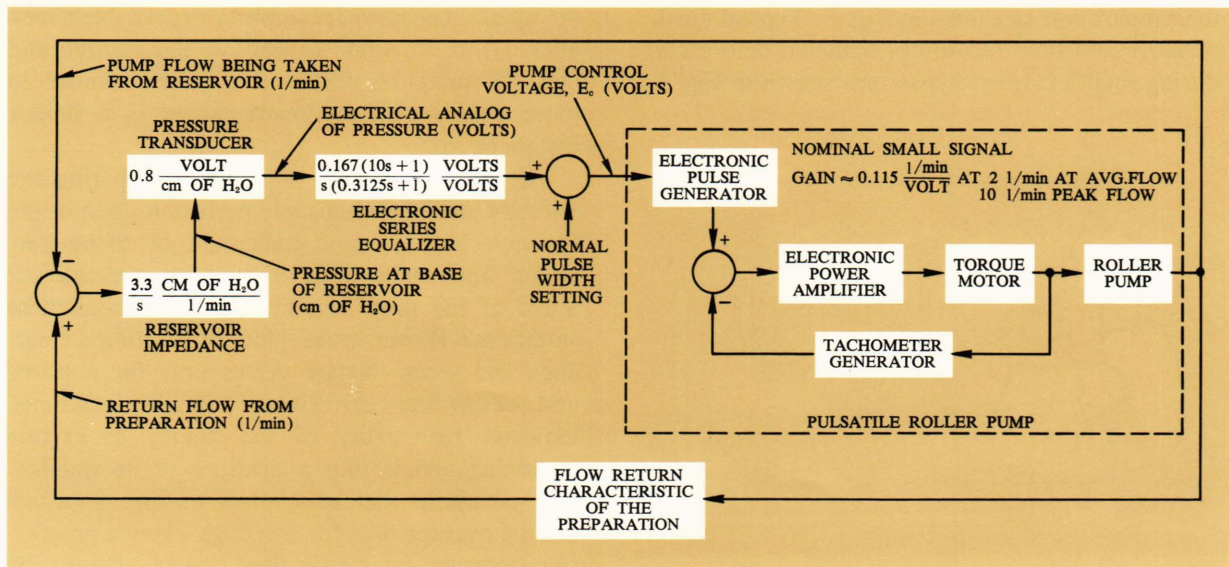


Fig. 4—Left ventricular bypass control system.

flow can be produced at flow rates continuously variable between 0 and 4 l/min.

The automatic flow regulation system is shown in block diagram form in Fig. 4. Basically, the pressure in the left atrium, which is the input chamber to the left ventricle, is sensed by a pressure transducer, integrated, and used to modulate the systolic duration of the pump output by adding a bias to the limited integrator. The atrial impedance of the animal is augmented by a small collapsible blood column that uses gravity to establish a linear relationship between atrial pressure and return blood volume while retaining a fluid system closed to the atmosphere. The series equalizer allows a vanishingly small atrial pressure change to automatically adjust the pump output to the value required to establish equilibrium with the return flow rate while maintaining a stable (non-oscillating) system.

Laboratory Results

An important design parameter for a mechanical blood pump is the minimization of blood damage owing to the pumping action. For the case of the roller pump, the principal source of hemolysis is believed to be the action of the rollers in occluding the tubing. Hemolysis testing of the pump was carried out *in vitro* (apart from the animal) in order to determine the effect of pulsatile flow on this parameter. The measure of blood damage (hemolytic index) was computed

by the formula shown in Eq. (1) based on the work of Allen⁵ at a mean flow rate of 2.0 l/min.

$$HI = \frac{100V_p(1 - HCT)}{Ft} [Hb] \quad (1)$$

where:

- HI = hemolytic index,
- V_p = system priming volume (liters),
- F = flow rate (l/min.),
- t = length of test (min.),
- HCT = initial hematocrit (percent of red blood cells),
- $[Hb]$ = difference in serum hemoglobin concentrations in grams per 100 liters between tested blood and a sample of the blood drawn immediately prior to test.

Steady-flow operation of the pump yielded a hemolytic index of 0.032 while pulsatile flow gave a value of 0.072 under these test conditions. Later, *in vivo* (animal) testing showed that serum hemoglobin levels after four hours of perfusion were not significantly affected by the mode of pumping. This result indicates that the animal was better able to remove free hemoglobin when pulsatile flow was used.

The pump was evaluated in full left-heart bypass tests on approximately 50 mongrel dogs during tests ranging from 4 to 18 hours duration. Circulation was supported in 15 dogs for periods in excess of 12 hours with the pump connected to

⁵ J. G. Allen, "Extracorporeal Circulation," Springfield, Ill., Charles C. Thomas, 1958, 515-538.

the preparation as shown in Fig. 5. Typical aortic pressure and flow recordings obtained before and during total left-heart bypass are shown in Fig. 6.

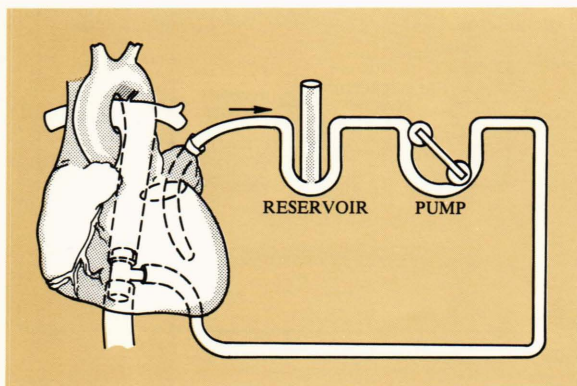


Fig. 5—Schematic of animal preparation. Blood is pumped from left atrium and ventricle into descending aorta. Aspiration of both atrium and ventricle insures total left-heart bypass.

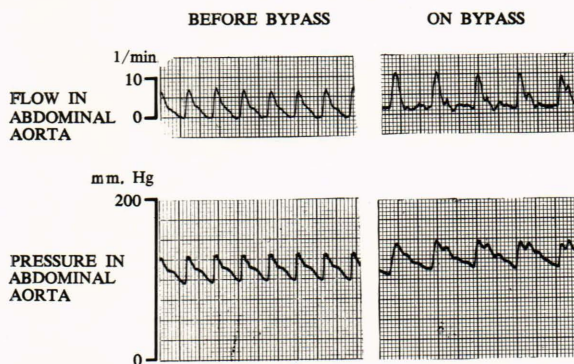


Fig. 6—Aortic pressure and flow tracings.

It can be seen that both the pressure and flow curves obtained during bypass closely resemble those produced by the dog's own left ventricle. The rate of pressure rise produced in the aorta of dogs undergoing pulsatile perfusion has varied between 1000 and 1500 mm Hg/sec compared to the range of 800 to 2000 mm Hg/sec found in the intact animal. Values of peripheral resistance obtained by taking the quotient of mean aortic pressure and mean aortic flow remained relatively constant for 10 to 12 hours in a typical test with pulsatile flow. Pressure and flow pulse characteristics maintained a normal appearance in every preparation throughout the course of perfusion. As

the animal began to succumb to irreversible shock after 12 to 15 hours of bypass, the systolic and diastolic pressures followed a course similar to those observed in an intact animal in a similar metabolic state.

The detailed results of studies comparing the effect of steady and pulsatile perfusion upon organ function and systemic indicators of tissue perfusion and metabolism have been presented.^{6,7} Some of the more significant results from these studies are shown in the plots of creatinine clearance and serum lactate versus time for pulsatile and steady-flow perfusion. Creatinine clearance indicates the ability of the kidney to excrete creatinine and is thus a measure of its viability. The creatinine clearance plots of Fig. 7, which are the average data for five dogs, show a progressive decrease for steady flow bypass—decreasing to less than 10 ml/min after four hours. However for pulsatile flow the creatinine clearance is maintained at its initial level during the first two hours of bypass and decreases to 30 ml/min after four hours. Hence these data show much more normal

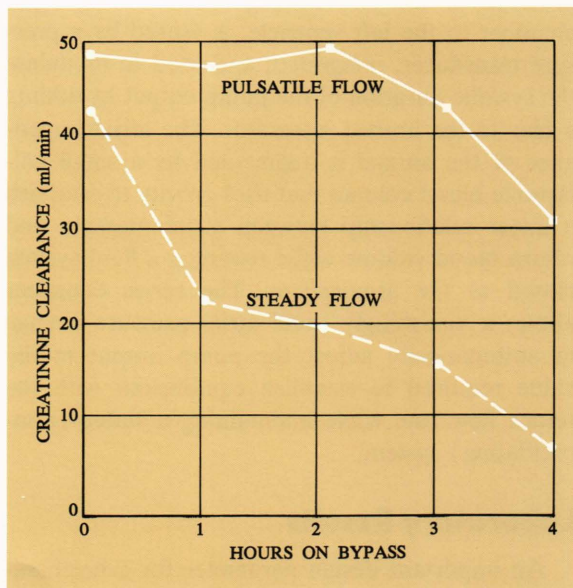


Fig. 7—Endogenous creatinine clearance during total left-heart bypass, comparing pulsatile and steady flow.

⁶ L. A. Jacobs, E. H. Klopp, W. Seamone, S. R. Topaz, and V. L. Gott, "Improved Organ Function during Cardiac Bypass with a Roller Pump Modified to Deliver Pulsatile Flow," *J. Thoracic and Cardiovascular Surg.* **58**, 1969, 703-712.

⁷ B. F. Hoffman, E. H. Klopp, L. A. Jacobs, W. Seamone, and V. L. Gott, "A Pulsatile Roller Pump for Cardiac Bypass," *IEEE Trans. Biomed. Eng.* In Press.

kidney function for pulsatile perfusion. Serum lactate concentration is a measure of cell perfusion. An increase above the control value is indicative of inadequate cell oxygenation. The serum lactate plots of Fig. 8, which are the average data for ten dogs on bypass for eight hours, show a marked increase of serum lactate concentration for steady flow over pulsatile perfusion, indicating more complete tissue perfusion during pulsatile flow. These results, together with other systemic indicators, clearly indicate the need for pulsatile perfusion by the mechanical blood pump.

In addition to the basic cardiovascular support studies, the automatic flow regulation feature has been evaluated *in vivo*. This system has provided stable control during 70 hours of full left-heart

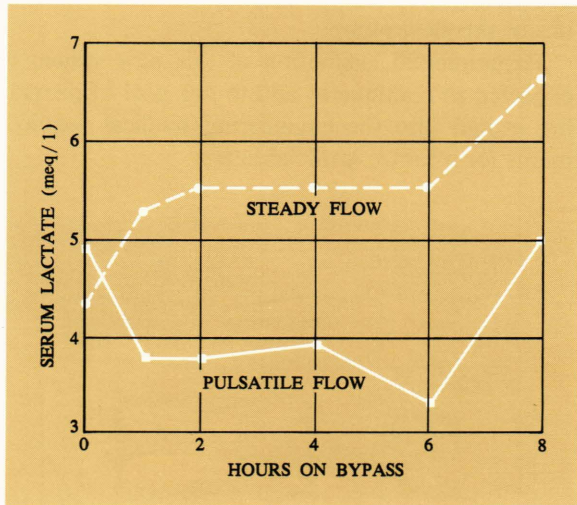


Fig. 8—Serum lactate concentrations during total left-heart bypass, comparing pulsatile and nonpulsatile flow.

bypass on 8 mongrel dogs. During the course of these experiments of 8 to 12 hours duration each, the atrial pressure was automatically controlled within 2 cm of H₂O of the selected reference level while the demand of the cardiovascular system varied between 500 and 2500 ml/min because of changes in the level of anesthesia and administration of fluids. In addition, experiments were performed to test the control system response to rapid changes. These excitations included an electrically generated step change of the atrial pressure reference, overinflation of the lungs, and administration of agents such as adrenalin to create rapid changes

in cardiac output. A typical comparison of *in vivo* results to *in vitro* experiments is shown in Fig. 9 for the case of the electrically generated step change in pressure reference level. The control system, which has a nominal 2-sec response time,

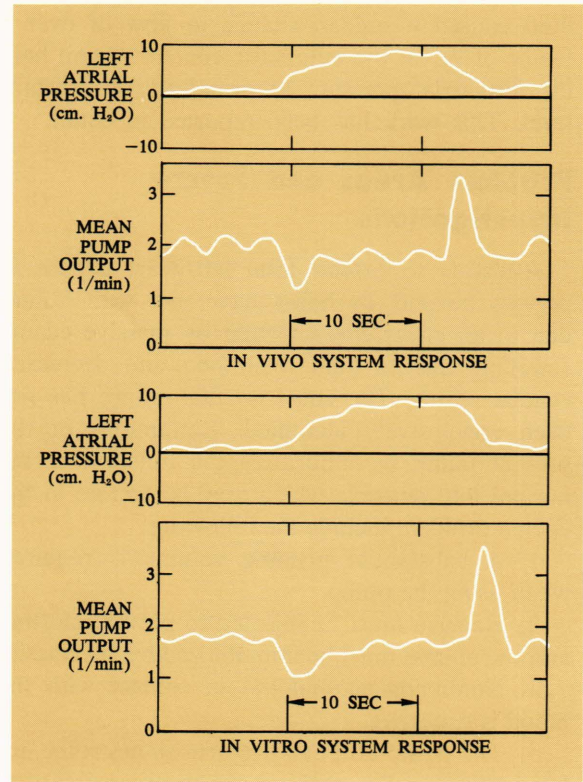


Fig. 9—*In vivo* and *in vitro* system response to a 7.5 cm step of H₂O atrial pressure command.

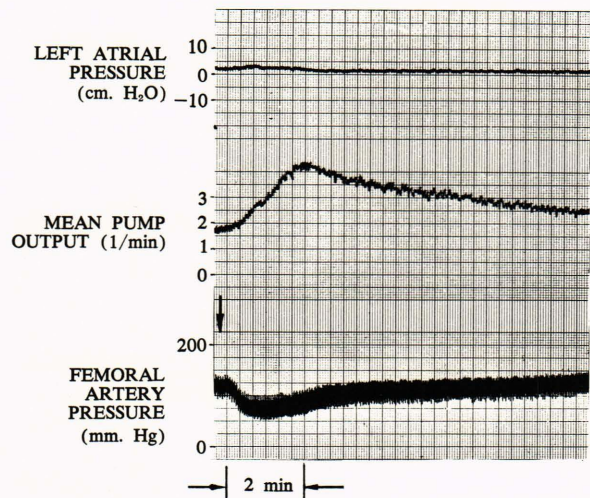


Fig. 10—System response to the intravenous administration of hypertonic urea.

has performed *in vivo* as predicted and is considered adequately responsive to both slow and rapid changes in the cardiac output of the preparation during left-heart bypass. Response of the system to the intravenous administration of hypertonic urea is shown in Fig. 10. Injection of this fluid caused a sudden change in flow of over a factor of 2, yet the automatic control system held the left atrial pressure at practically a constant level. This work has been reported in detail.⁸

Problem Areas and Future Investigations

Attempts to extend total left-heart bypass to periods beyond 18 hours have met with failure due to an effect characterized by massive edema (swelling due to fluid retention) and decreased venous return. The cause of this failure has not been conclusively identified. Limitations of the present pump in duplicating the function of the normal left ventricle which may be factors in the edema problem include the following:

1. A substantial priming volume is required when using the pump.
2. Heparin must be injected to prevent clotting and the animal must be immobilized by anesthesia.
3. Nonbiological material in contact with the blood is excessive.
4. The pump output waveform shows some dependence on roller position due to distensibility of the tube ahead of the roller. Also, a reduced pulse amplitude region occurs as the lead roller leaves the tube.
5. The blood is drawn from the atrium (pump input) in sharp pulses.

In order to assess the contribution of the above anomalies to the edema problem, a new diaphragm pump which reduces blood contact with prosthetic surfaces is being developed. This pump together with its actuation system is shown in Fig. 11. In this approach the blood pump is placed inside the thoracic (chest) cavity and blood contact with prosthetic surfaces is limited to a few inches of tubing. The proposed technique uses clinical prosthetic heart valves and a collapsible tube which, as far as the blood is concerned, is contracted in a manner similar to natural heart action.

⁸ E. H. Klopp, L. A. Jacobs, B. F. Hoffman, W. Seamone, and V. L. Gott, "Use of Left Atrial Pressure as a Control Parameter for Left-Heart Bypass," *Trans. Amer. Soc. Artif. Intern. Organs*, **XV**, 1969, 391-397.

Pumping action of the new artificial ventricle is controlled by an actuator located on the external side of the rib cage. The actuation is transmitted to the blood pump by a saline solution. The mechanical connections between the heart pump and the actuator are very short and very rigid in order to achieve rapid initial ejection rate of the artificial ventricle. Thus, displacement of the heart pump and displacement of the actuator are essentially identical. The electromechanical drive for the actuator is to be derived from the same DC torque motor used for the roller pump.

Preliminary results from tests conducted on the new diaphragm pump indicate the edema problem appears significantly reduced over similar tests conducted with the roller pump. Much additional testing must be conducted, however, in order to adequately assess the capabilities and characteristics of this new pump.

Experimental evaluation of this new system is expected to continue to add to our goal of providing insight into the engineering/medical requirements for a future artificial heart.

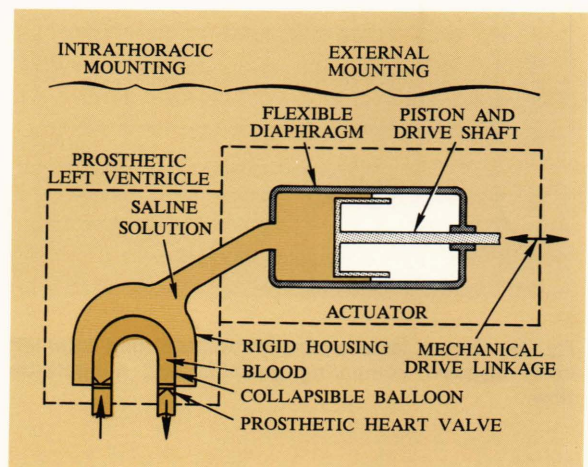


Fig. 11—Actuation concept for intrathoracic pump.

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